OMEROS CORP Form 10-Q May 11, 2015 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q

(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT Х OF 1934 For the quarterly period ended March 31, 2015 or TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT ... OF 1934 For the transition period from to Commission file number: 001-34475 OMEROS CORPORATION (Exact name of registrant as specified in its charter) Washington 91-1663741 (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification Number) 201 Elliott Avenue West 98119 Seattle, Washington (Address of principal executive offices) (Zip Code) (206) 676-5000 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer Accelerated filer x

Non-accelerated filer "(Do not check if a smaller reporting company) Smaller reporting ... company

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

As of May 7, 2015, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 37,832,261.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, which are subject to the "safe harbor" created by those sections for such statements. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are "forward-looking statements." Terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "predict," "project," "shoul similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

our plans for sales, marketing and distribution of Omidria^T(phenylephrine and ketorolac injection) 1%/0.3% in the U.S. and for sales, marketing and distribution in the European Union, or EU, and other international territories; our ability to receive regulatory approval for our Marketing Authorisation Application, or MAA, for Omidria in the EU;

our expectation that we will receive an opinion on the MAA from the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, in the first half of 2015;

our ability to enter into acceptable arrangements with potential corporate partners, including with respect to Omidria; our expectations regarding the clinical, therapeutic and competitive benefits of Omidria and our product candidates; our anticipated future sales from Omidria and our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes;

our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaboration or licensing arrangements or asset sales;

our anticipation that we will rely on contract manufacturers to develop and manufacture our product candidates and to manufacture Omidria for commercial sale;

our expectations about the commercial competition that Omidria and our product candidates may face;

our expectations regarding transitional pass-through reimbursement status for Omidria granted by the Centers for Medicare and Medicaid Services, or CMS, including that transitional pass-through reimbursement status for Omidria will remain in effect until December 31, 2017;

the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs, products and product candidates;

our ability to design and successfully complete clinical trials and other studies for our products and product candidates, including our Phase 2 clinical trials for OMS721 and OMS824;

whether the requested access to OMS721 for compassionate use will be approved;

our ability to recommence active enrollment in our Phase 2 clinical trial of OMS824 in Huntington's disease or initiate further clinical studies in either our OMS824 Huntington's or schizophrenia programs;

whether there may be an opportunity to have OMS103 produced and commercialized by a registered outsourcing facility;

whether our OMS103 Phase 3 clinical program in arthroscopic partial meniscectomy surgery may be redesigned to include reduction of early postoperative pain as the primary endpoint;

our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources; and

our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results

of Operations" and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or developments anticipated may not be realized or, even if substantially

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realized, they may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this

Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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PART I—FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS OMEROS CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except share and per share data)

(unaudited)

	March 31, 2015		December 2014	31,
Assets				
Current assets:				
Cash and cash equivalents	\$1,441		\$354	
Short-term investments	68,621		6,532	
Receivables	538		392	
Inventory	566		568	
Prepaid expense	1,784		1,191	
Other current assets	116		120	
Total current assets	73,066		9,157	
Property and equipment, net	727		782	
Restricted cash	679		679	
Other assets	439		472	
Total assets	\$74,911		\$ 11,090	
Liabilities and shareholders' equity (deficit)				
Current liabilities:				
Accounts payable	\$4,611		\$4,915	
Accrued expenses	6,438		7,070	
Current portion of notes payable, net of discount	9,019		6,446	
Total current liabilities	20,068		18,431	
Notes payable, net of current portion and discount	23,906		26,263	
Deferred rent	9,091		9,050	
Commitments and contingencies (Note 8)				
Shareholders' equity:				
Preferred stock, par value \$0.01 per share, 20,000,000 authorized; none issued and				
outstanding at March 31, 2015 and December 31, 2014			_	
Common stock, par value \$0.01 per share, 150,000,000 authorized; 37,825,261 and				
34,185,464 issued and outstanding at March 31, 2015 and December 31, 2014,	378		342	
respectively				
Additional paid-in capital	368,183		285,050	
Accumulated deficit	(346,715)	(328,046)
Total shareholders' equity (deficit)	21,846		(42,654)
Total liabilities and shareholders' equity (deficit)	\$74,911		\$11,090	
See notes to consolidated financial statements				

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OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (In thousands, except share and per share data) (unaudited)

	Three Months Ended March 31,			
	2015		2014	
Revenues				
Product sales	\$238		\$—	
Grant revenue	150		100	
Total revenue	388		100	
Costs and expenses:				
Cost of product sales	11		—	
Research and development	9,318		12,017	
Selling, general and administrative	8,989		3,767	
Total costs and expenses	18,318		15,784	
Loss from operations	(17,930)	(15,684)
Interest expense	(957)	(672)
Investment income and other income (expense), net	218		(286)
Net loss	\$(18,669)	\$(16,642)
Comprehensive loss	\$(18,669)	\$(16,642)
Basic and diluted net loss per share	\$(0.51)	\$(0.54)
Weighted-average shares used to compute basic and diluted net loss per share	36,483,559)	30,897,039)
See notes to consolidated financial statements				

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OMEROS CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (In thousands) (unaudited)

	Three Months Ended March 31,		
	2015	2014	
Operating activities:			
Net loss	\$(18,669)	\$(16,642)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of assets		(9)
Depreciation and amortization	55	82	
Stock-based compensation expense	2,517		